

SURGICAL SERVICES STANDARD ADVISORY COMMITTEE (SSSAC) MEETING

Thursday, October 20, 2005

State Secondary Complex
General Office Building (GOB)
7150 Harris Drive
Conference Room A
Lansing (Dimondale), Michigan

APPROVED MINUTES

I. Call to Order.

Chairperson Miller called the meeting to order at 9:00 a.m.

a. Members Present and Organizations Represented:

Cheryl Miller, Trinity Health (Chairperson)
Eric Barnaby, Foote Health System (Alternate)
Evelyn Bochenek, RN, MSN, Sparrow Hospital
Charles Dobis, Michigan Ambulatory Surgery Association
John Fox, MD, Priority Health
Linda Fox, RN, Spectrum Health (Alternate)
Toshiki Masaki, Michigan Manufacturers Association
Richard Mata, Michigan State AFL-CIO
Rand O'Leary, Borgess Medical Center
Krishna Sawhney, MD, Henry Ford Health System
Debra Stephenson, BSN-RN, MBA, CNOR, McLaren Health Care
Walter M. Whitehouse, Jr., MD, The Saint Joseph Mercy Health System
Robert Wolford, Michigan Medical Group Management Association
George Yoo, MD, Barbara Ann Karmanos Cancer Institute

b. Members Absent and Organizations Represented:

Lowell Bursch, MD, Spectrum Health
Kim Meeker, RN, BSN, MBA, Foote Health System

c. Staff Present:

Lakshmi Amarnath
Tom Freebury (Arrived at 9:54 a.m.)
Larry Horvath
John Hubinger
Andrea Moore
Stan Nash
Gaye Tuttle
Matt Weaver

II. Review of Agenda and Distributed Materials.

Chairperson Miller reviewed the agenda and the distributed materials. Motion by Dr. Whitehouse, seconded by Mr. Mata, to accept the Agenda as presented. Motion Carried.

III. Conflicts of Interests.

No conflicts were noted.

IV. Review of Minutes – October 12, 1005.

Motion by Dr. Sawhney, seconded by Ms. Bochenek, to accept the Minutes as presented. Motion Carried.

V. Draft Language (Attachment A).

Section 1

No changes.

Section 2

Line 67 – insert “operating” and strike “an endoscopy or cystoscopy.”

Line 80 – add “This term also includes the change of a dedicated endoscopy or cystoscopy operating room to a non-dedicated OR.”

Line 147 – Add “This term also includes dedicating an OR to a dedicated endoscopy or cystoscopy operating room.”

Section 3

No changes.

Section 4

No changes.

Section 5

Motion by Mr. Mata, seconded by Ms. Fox, to reconsider the volume levels. Motion Fails (6 – For and 7 – Against).

Section 6

Line 409 – change to read “An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall submit notification to the Department on a form provided by the Department. An applicant under this subsection shall not be required to comply with subsections (1) and (2).

Line 379 – change “two, three, or four” to read “three, four or five.”

Line 389 – strike “in a facility that performs only outpatient surgery.”

Motion by Dr. Sawhney, seconded by Dr. Fox, to accept Section 6 as amended. Motion Carried.

Public Participation in Discussion:

Melissa Cupp, Wiener Associates

Robert Meeker, Spectrum Health

Amy Barholz, Michigan Hospital Association

Section 7

Line 481 - change “two, three, or four” to read “three, four or five.”

Line 491 - strike “in a facility that performs only outpatient surgery.”

Line 476 – change “at a licensed hospital” to read “from one licensed hospital site to another licensed hospital site.”

Motion by Dr. Sawhney, seconded by Dr. Whitehouse, to accept Section 7 as amended. Motion Carried.

Section 8

No changes.

Section 9

Motion by Mr. Wolford, seconded by Mr. Masaki, to accept Section 9 as presented. Motion Carried.

Break from 10:23 a.m. to 10:30 a.m.

Public Participation in Discussion:

Julie Green, Grand Valley Surgical Center
Amy Barholz, Michigan Hospital Association
Kathy Uecker, Healthcare Midwest
Robert Meeker, Spectrum Health

Section 10

No changes.

Section 11

Line 644 – change “(either cases or hours)” to “(cases and/or hours).”

Section 12

No changes.

Section 10 - continued

Change the number of Section 10(d)(xii) to be Section 10(f).

Public Participation in Discussion:

Barbara Jackson, Economic Alliance of Michigan

Entire Standards

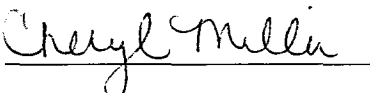
Motion by Dr. Fox, seconded by Dr. Whitehouse, to reconsider the October 12, 2005 Motion of Dr. Yoo, seconded by Dr. Fox, to accept the Standards as revised. Motion Carried.

Motion by Dr. Sawhney, seconded by Ms. Stephenson, to accept the revision to the Standards discussed and forward the language to the Commission at it's next meeting. Motion Carried.

VI. Adjournment.


Motion by Dr. Fox, seconded by Mr. Wolford, to adjourn the meeting at 11:10 p.m. Motion Carried.

MINUTES APPROVED AND ACCEPTED BY:



Cheryl Miller, Chairperson
Surgical Services Standard Advisory Committee

11-17-05
Date



Brenda Rogers
Special Assistant to CON Commission

11-16-05
Date

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the Certificate of Need CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which ~~involve~~ involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgical center ~~CERTIFIED UNDER TITLE XVIII~~, or a SURGICAL DEPARTMENT OF A hospital licensed under Part 215 of the Code performing ~~AND OFFERING~~ inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, and ~~10~~ 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Section 910, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(6)(a) These standards shall apply to the review of all Certificate of Need applications for surgical services for which the Director of the Department of Community Health has not made a final decision under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.~~

~~(b) In the case of an application which has been deemed submitted, but which has not received a final decision by the Director on the effective date of these standards, an applicant may request, and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.~~

~~(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8), being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.~~

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

For Surgical Services SAC Consideration on 10/20/05

Italicized Language was approved by the CON Commission through Proposed Action on 9/13/05 and is shown for informational purposes only.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(c) "Burn care," for purposes of these standards, means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(D) "CERTIFICATE OF NEED COMMISSION" OR "COMMISSION" MEANS THE COMMISSION CREATED PURSUANT TO SECTION 22211 OF THE CODE, BEING SECTION 333.22211 OF THE MICHIGAN COMPILED LAWS.

(dE) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(eF) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(fG) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(H) "DEDICATED ENDOSCOPY OR CYSTOSCOPY ROOM" MEANS AN ENDOSCOPY OR CYSTOSCOPY ROOM USED EXCLUSIVELY FOR ENDOSCOPY OR CYSTOSCOPY CASES.

(gl) "Department" means the Michigan Department of Community Health (MDCH).

(hJ) "Emergency Room," for purposes of Section 6(2)(b) of these standards only, means a designated area in a licensed hospital and recognized by the Department of Consumer and Industry Services as having met the staffing and equipment requirements for the treatment of emergency patients.

(iK) "Endoscopy" means visual inspection of any cavity **PORTION** of the body by means of an endoscope.

(jL) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(kM) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is licensed as part of a licensed hospital site, or a LICENSED freestanding surgical outpatient facility, or that is A certified as an ambulatory surgical center ASC.

(lN) "Expand a surgical service" means the addition of one or more operating rooms **OR THE ADDITION OF ONE OR MORE DEDICATED ENDOSCOPY/CYSTOSCOPY ROOMS** at an existing surgical service.

(mO) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned by, AND operated, and licensed as a part of a hospital at a licensed hospital site.

(nP) "Hospital" means a health facility licensed under Part 215 of the Code.

(oQ) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(pR) "Initiate a surgical service" means to begin operation of a surgical facility at a site that does HAS not perform OFFERED surgical services WITHIN THE 12-MONTH PERIOD IMMEDIATELY PRECEDING as of the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(qS) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(T) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND 1396R-8 TO 1396V.

(U) "METROPOLITAN STATISTICAL AREA COUNTY" MEANS A COUNTY LOCATED IN A METROPOLITAN STATISTICAL AREA AS THAT TERM IS DEFINED UNDER THE "STANDARDS FOR DEFINING METROPOLITAN AND MICROPOLITAN STATISTICAL AREAS" BY THE STATISTICAL

POLICY OFFICE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS OF THE UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, 65 F.R. P. 82238 (DECEMBER 27, 2000) AND AS SHOWN IN APPENDIX A.

(V) "MICROPOLITAN STATISTICAL AREA COUNTY" MEANS A COUNTY LOCATED IN A MICROPOLITAN STATISTICAL AREA AS THAT TERM IS DEFINED UNDER THE "STANDARDS FOR DEFINING METROPOLITAN AND MICROPOLITAN STATISTICAL AREAS" BY THE STATISTICAL POLICY OFFICE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS OF THE UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, 65 F.R. P. 82238 (DECEMBER 27, 2000) AND AS SHOWN IN APPENDIX A.

(rW) "Offer" means to perform surgical services.

(sX) "Operating room" or "OR," for purposes of these standards, means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. THIS TERM DOES NOT INCLUDE PROCEDURE ROOMS.

(tY) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(uZ) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(AA) "PROCEDURE ROOM" MEANS A ROOM IN A SURGICAL FACILITY CONSTRUCTED AND EQUIPPED TO PERFORM SURGICAL PROCEDURES AND NOT LOCATED ON A STERILE CORRIDOR.

(vBB) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different **LOCATION CURRENTLY OFFERING SURGICAL SERVICES** site within the relocation zone.

(wCC) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a nonrural METROPOLITAN STATISTICAL AREA county, or a 20-mile radius if an existing surgical service is located in a rural OR MICROPOLITAN STATISTICAL AREA county.

(xDD) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(yEE) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. The term does not include the renovation of an existing surgical service or one or more operating rooms.

(zFF) "Rural county" means a county not located in a metropolitan STATISTICAL area OR MICROPOLITAN STATISTICAL AREAS as that ~~THOSE~~ termS is ARE defined pursuant UNDER to the "Revised standards for defining metropolitan AND MICROPOLITAN STATISTICAL areas in the 1990's" by the Statistical STATISTICAL Policy POLICY Office OFFICE of the Office OFFICE of Information Information and Regulatory Regulatory Affairs Affairs of the United States Office of Management MANAGEMENT and BudgetBUDGET, 55-65 F.R. p. 42154 82238 (March DECEMBER 2730, 19902000) AND AS SHOWN IN APPENDIX A.

For Surgical Services SAC Consideration on 10/20/05

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~~(aaGG)~~ "Sterile corridor," for purposes of these standards, means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

~~(bbHH)~~ "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

~~(ccII)~~ "Surgical facility" means either:

(i) a licensed freestanding surgical outpatient facility FSOF;

(ii) a certified ambulatory surgical center ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

~~(ddJJ)~~ "Surgical service" means performing surgery in a surgical facility.

~~(eeKK)~~ "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(LL) "VERIFIABLE DATA" MEANS SURGICAL DATA (CASES AND/OR HOURS) FROM THE MOST RECENT ANNUAL SURVEY OR MORE RECENT DATA THAT CAN BE VALIDATED BY THE DEPARTMENT.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms AND VERIFIABLE DATA pursuant to subsection (2) TO DETERMINE and the number of surgical cases, or hours of use, OR BOTH, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. COMPLIANCE WITH CON MINIMUM VOLUME REQUIREMENTS ESTABLISHED BY THESE STANDARDS SHALL BE DETERMINED BASED ON THE AVERAGE NUMBER OF SURGICAL CASES, HOURS OF USE, OR BOTH, PER OPERATING ROOM OF THE SURGICAL SERVICE AS PERMITTED BY THESE STANDARDS.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

~~(iv) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision.~~

~~(v) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.~~

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), AND (iii), and (iv).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least ~~1,200~~ 1,128 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural OR MICROPOLITAN STATISTICAL AREA county that does not offer surgical services as of the date an application is submitted to the Department.

~~(3) If the number of surgical cases projected under subsection (1) includes surgical cases performed at an existing surgical facility(s),~~ An applicant shall demonstrate that it meets the requirements of Section 1011(2) FOR THE NUMBER OF SURGICAL CASES PROJECTED UNDER SUBSECTION (1).

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200~~1,128~~ surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, or

(ii) in a hospital, ~~1,600~~1,219 hours of use or in an FSOF or ASC, ~~1,800~~ hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room for the most recent 12-month period for which verifiable data is available to the Department. OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,625 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,219. (FOR EXAMPLE: USING 410 INPATIENT HOURS AND 915 OUTPATIENT HOURS WOULD EQUATE TO $410/1,625 + 915/1,219 = 0.25 + 0.75 = 1.00$ OR.), OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND

SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,625 PLUS THE OUTPATIENT CASES DIVIDED BY 1,128. (FOR EXAMPLE: USING 410 INPATIENT HOURS AND 850 OUTPATIENT CASES WOULD EQUATE TO $410/1,625 + 850/1,128 = 0.25 + 0.75 = 1.00$ OR.)

(b) All PROPOSED operating rooms, existing and proposed, are projected to perform an average of at least:

(i) 1,200/1,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, or

(ii) in a hospital, 1,600/1,125 hours of use or in an FSO/ OR ASC, 1,800 hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter, OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

(2) AN APPLICANT PROPOSING TO ADD ONE OR MORE OPERATING ROOMS AT A LICENSED HOSPITAL AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) THE APPLICANT HAS TWO, THREE, OR FOUR ORS AT THE LICENSED HOSPITAL.

(B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:

(i) 909 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(ii) 1,300 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.

(C) All PROPOSED OPERATING ROOMS ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:

(i) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR

(ii) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural OR MICROPOLITAN STATISTICAL AREA county that currently has only one operating room.

For Surgical Services SAC Consideration on 10/20/05

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(34) If the number of surgical cases, or hours of use, projected under subsection (1) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an applicant shall demonstrate that it meets the requirements of Section 1011(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (1).

Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or more operating rooms

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:
(i) 1,2001,042 surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, or

(ii) in a hospital, 1,6001,125 hours of use, or in an FSOE or ASC, 1,800 hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room for the most recent 12-month period for which verifiable data is available to the Department, OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.).

(b) All operating rooms, existing and replaced~~proposed~~, are projected to perform an average of at least:

(i) 1,2001,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, or

(ii) in a hospital, 1,6001,125 hours of use, or in an FSOE or ASC, 1,800 hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter., OR

(III) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), OR

(IV) A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:

(A) THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

(2) AN APPLICANT PROPOSING TO REPLACE ONE OR MORE OPERATING ROOMS AT A LICENSED HOSPITAL AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE FOLLOWING:

- (A) THE APPLICANT HAS TWO, THREE, OR FOUR ORS AT THE LICENSED HOSPITAL.
- (B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:
 - (I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR
 - (II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.
- (C) ALL OPERATING ROOMS, EXISTING AND REPLACED, ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:
 - (I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR
 - (II) 1,200 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(23)(a) SubsectionS (1) AND (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural OR MICROPOLITAN STATISTICAL AREA county and has one or two operating rooms.

— (b) Subsection (1) shall not apply if the proposed project involves replacing one or two operating rooms at the same licensed hospital site if the surgical facility is a hospital that:

- (i) is located in a nonrural county;
- (ii) has an emergency room at the same licensed hospital site as the operating rooms;
- (iii) has exactly two operating rooms; and
- (iv) has performed at least 1,200 surgical cases, or at least 1,600 hours of use, per year for the most recent 12-month period for which verifiable data is available to the Department.

(4) SUBSECTIONS (1) AND (2) SHALL NOT APPLY TO THOSE HOSPITALS LICENSED UNDER PART 215 OF PA 368 OF 1978, AS AMENDED THAT HAD FEWER THAN 70 LICENSED BEDS ON DECEMBER 1, 2002 PROVIDED THE NUMBER OF ORS AT THE SURGICAL SERVICE HAS NOT INCREASED AS OF MARCH 31, 2003, AND THE LOCATION DOES NOT CHANGE.

(5) AN APPLICANT PROPOSING TO DESIGNATE AN OR AS AN ENDOSCOPY OR CYSTOSCOPY ROOM USED EXCLUSIVELY FOR ENDOSCOPY OR CYSTOSCOPY CASES SHALL SUBMIT NOTIFICATION TO THE DEPARTMENT ON A FORM PROVIDED BY THE DEPARTMENT.

Section 7. Requirements for approval for applicants proposing to relocate aN EXISTING surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate aN EXISTING surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility **FROM WHICH ONE OR MORE ORS ARE PROPOSED** to be relocated have performed an average of at least:

(Ia) 1,200-1,042 surgical cases PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR

(Iib) in a hospital, 1,600-1,125 hours of use, or in an FSOE or ASC, 1,800 hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR for the most recent 12-month period for which verifiable data is available to the Department.

(III) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:**

(A) **THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.)** OR

(IV) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:**

(A) **THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)**

(B4) All operating rooms, existing and **proposed RELOCATED**, are projected to perform an average of at least:

(Ia) 1,200-1,042 surgical cases PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, or

(Iib) in a hospital, 1,600-1,125 hours of use, or in an FSOE or ASC, 1,800 hours of use FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY per year per operating room in the second twelve months of operation, and annually thereafter.

(III) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF INPATIENT HOURS OF USE AND OUTPATIENT HOURS OF USE AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:**

(A) **THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT HOURS DIVIDED BY 1,125. (FOR EXAMPLE: USING 375 INPATIENT HOURS AND 844 OUTPATIENT HOURS WOULD EQUATE TO $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.)** OR

(IV) **A LICENSED HOSPITAL THAT PROVIDES BOTH INPATIENT AND OUTPATIENT SURGERY MAY USE A WEIGHTED AVERAGE OF HOURS OF USE (INPATIENT SURGICAL VOLUME) AND SURGICAL CASES (OUTPATIENT SURGICAL VOLUME) AS BILLED BY THE FACILITY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER AND CALCULATED AS FOLLOWS:**

(A) **THE NUMBER OF OPERATING ROOMS SHALL BE THE SUM OF THE INPATIENT HOURS OF USE DIVIDED BY 1,500 PLUS THE OUTPATIENT CASES DIVIDED BY 1,042. (FOR EXAMPLE: USING**

375 INPATIENT HOURS AND 785 OUTPATIENT CASES WOULD EQUATE TO $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)

(54) AN APPLICANT PROPOSING TO RELOCATE ONE OR MORE OPERATING ROOMS AT A LICENSED HOSPITAL AND IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY OR THE APPLICANT IS LOCATED IN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST RECENT FEDERAL DECENNIAL CENSUS SHALL DEMONSTRATE EACH OF THE FOLLOWING:

- (A) THE APPLICANT HAS TWO, THREE OR FOUR ORS AT THE LICENSED HOSPITAL.
- (B) ALL EXISTING OPERATING ROOMS HAVE PERFORMED AN AVERAGE OF AT LEAST:
 - (I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, OR
 - (II) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.
- (C) ALL OPERATING ROOMS, EXISTING AND RELOCATED, ARE PROJECTED TO PERFORM AN AVERAGE OF AT LEAST:
 - (I) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER, OR
 - (II) 1,200 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER YEAR PER OPERATING ROOM IN THE SECOND TWELVE MONTHS OF OPERATION, AND ANNUALLY THEREAFTER.

(56) If the number of surgical cases projected under subsection (4) includes surgical cases, or hours of use, performed at an existing surgical facility(s), an applicant shall demonstrate that it meets the requirements of Section 1011(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE PROJECTED UNDER SUBSECTION (4).

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:

(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, ON OR after the effective date of these standards JANUARY 27, 1996, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

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— (6) Subsection (5) shall not apply if the proposed project involves the acquisition of both of the operating rooms of an existing surgical service of a hospital if the hospital from which the service being acquired is: (A) located in a nonrural county, (b) has an emergency room at the same licensed hospital site as the operating rooms, (c) has exactly two operating rooms, and (d) has performed at least 1,200 surgical cases or at least 1,600 hours of use per year for the most recent 12-month period for which verifiable data is available to the department. The operating rooms acquired under this subsection must remain part of a surgical service of a licensed hospital.

(6) SUBSECTION (15) SHALL NOT APPLY TO THOSE HOSPITALS LICENSED UNDER PART 215 OF PA 368 OF 1978, AS AMENDED THAT HAD FEWER THAN 70 LICENSED BEDS ON DECEMBER 1, 2002 PROVIDED THE NUMBER OF ORS AT THE SURGICAL SERVICE HAS NOT INCREASED AS OF MARCH 31, 2003, AND THE LOCATION DOES NOT CHANGE.

Section 9. Requirements for approval -- all applicants

Sec. 9. AN APPLICANT SHALL PROVIDE EVIDENCE OF PARTICIPATION IN MEDICAID OR IN MEDICAID MANAGED CARE PRODUCTS OR ATTESTATION THAT THE APPLICANT HAS BEEN UNABLE TO CONTRACT AT CURRENT MEDICAID RATES VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. BY PROVIDING A SIGNED AFFIDAVIT, AN APPLICANT THAT IS AN ASC OR FSO OF SHALL DEMONSTRATE, BY PROVIDING A SIGNED AFFIDAVIT, A WILLINGNESS TO PARTICIPATE WHEN ACCEPTED BY MEDICAID. AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL PROVIDE A SIGNED AFFIDAVIT STATING THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 910. Project delivery requirements -- terms of approval for all applicants

Sec. 910. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of Certificate of Need CON approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards.
- (c) Compliance with the following terms of approval, as applicable:
 - (i) The approved services and/or operating rooms shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.
 - (ii) THE APPLICANT'S ORS AND THEIR DESIGNATION OF ORS AS DEFINED BY THE STANDARDS SHALL NOT BE CHANGED WITHOUT PRIOR NOTIFICATION TO THE DEPARTMENT.
 - (iii) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
 - (A) not deny surgical services to any individual based on ability to pay or source of payment;
 - (B) provide surgical services to any individual based on the clinical indications of need for the service.
 - (C) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iiiV) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by

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the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) Within 10 days after initiation of the service, an THE applicant shall provide the Department with a notice stating the first date on which the approved service was initiated BECAME OPERATIONAL, AND SUCH NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(XII) AN APPLICANT SHALL PARTICIPATE IN MEDICAID OR IN MEDICAID MANAGED CARE PRODUCTS AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER OR ATTEST THAT THE APPLICANT HAS BEEN UNABLE TO CONTRACT AT CURRENT MEDICAID RATES.

(e) For purposes of evaluating subsection (d), the Department shall consider it *prima facie* evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

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Section 1011. Documentation of projections

Sec. 1011. (1) An applicant required to project volumes of service under the applicable sections of these standards shall specify how the volume projections were developed **AND SHALL INCLUDE ONLY THOSE SURGICAL CASES PERFORMED IN AN OR**. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(2) If a projected number of surgical cases, or hours of use, **UNDER SUBSECTION (1)** includes surgical cases, or hours of use, performed at an **OTHER** existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will **CONTINUE TO** be in compliance with the volume requirements (**EITHER CASES OR HOURS**) applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

- (a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.
- (b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.
- (c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.
- (d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.
- (e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 1112. Effect on prior Certificate of Need CON review standards; comparative reviews

Sec. 1112. (1) These Certificate of Need **CON** review standards supercede and replace the Certificate of Need **CON** Review Standards for Surgical Facilities approved by the Certificate of Need **CON** Commission on December 12, 1995 **SEPTEMBER 22, 1998** and effective on January 27, 1996 **DECEMBER 10, 1998**.

- (2) Projects reviewed under these standards shall not be subject to comparative review.

**CON REVIEW STANDARDS
FOR SURGICAL SERVICES**

RURAL MICHIGAN COUNTIES ARE AS FOLLOWS:

ALCONA	HILLSDALE	OGEMAW
ALGER	HURON	ONTONAGON
ANTRIM	IOSCO	OSCEOLA
ARENAC	IRON	OSCODA
BARAGA	LAKE	OTSEGO
CHARLEVOIX	LUCE	PRESQUE ISLE
CHEBOYGAN	MACKINAC	ROSCOMMON
CLARE	MANISTEE	SANILAC
CRAWFORD	MASON	SCHOOLCRAFT
EMMET	MONTCALM	TUSCOLA
GLADWIN	MONTMORENCY	
GOGEBIC	OCEANA	

MICROPOLITAN STATISTICAL AREA MICHIGAN COUNTIES ARE AS FOLLOWS:

ALLEGAN	GRATIOT	MECOSTA
ALPENA	HOUGHTON	MENOMINEE
BENZIE	ISABELLA	MIDLAND
BRANCH	KALKASKA	MISSAUKEE
CHIPPEWA	KEWEENAW	ST. JOSEPH
DELTA	LEELANAU	SHIAWASSEE
DICKINSON	LENAAWEE	WEXFORD
GRAND TRAVERSE	MARQUETTE	

METROPOLITAN STATISTICAL AREA MICHIGAN COUNTIES ARE AS FOLLOWS:

BARRY	IONIA	NEWAYGO
BAY	JACKSON	OAKLAND
BERRIEN	KALAMAZOO	OTTAWA
CALHOUN	KENT	SAGINAW
CASS	LAPEER	ST. CLAIR
CLINTON	LIVINGSTON	VAN BUREN
EATON	MACOMB	WASHTENAW
GENESEE	MONROE	WAYNE
INGHAM	MUSKEGON	

SOURCE:

65 F.R., P. 82238 (DECEMBER 27, 2000)
STATISTICAL POLICY OFFICE
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
UNITED STATES OFFICE OF MANAGEMENT AND BUDGET